HEALTH OCCUPATIONS

ADMINISTRATIVE LAW – BOARD OF PHARMACY – DISPENSING OF PRESCRIPTION DRUGS BY PHYSICIANS, DENTISTS, AND PODIATRISTS

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When a doctor writes a prescription, a patient will typically take that prescription to a pharmacy. The pharmacist may only fill the prescription and dispense the prescription drugs if he or she has a license from the Maryland Board of Pharmacy (the "Board"). *See* Md. Code Ann., Health Occupations ("HO") § 12-301(a) (2014 Repl. Vol.). Under certain circumstances, physicians, dentists, and podiatrists may also fill prescriptions and dispense prescription drugs. *See* HO § 12-102(c). As long as these practitioners comply with a number of other statutory and regulatory guidelines, they may "personally prepar[e] and dispens[e]" drugs that they have prescribed for their own patients if they (1) demonstrate to the satisfaction of their respective licensing boards that their dispensing of prescription drugs "is in the public interest" and (2) receive a written permit from that board. HO § 12-102(c)(2)(ii)1.

On behalf of the Board, your predecessor, Michael Souranis, asked three questions about this statutory scheme. First, he asked whether there are any restrictions on the ability of the Department of Health and Mental Hygiene ("DHMH") or the Board to issue regulations clarifying the meaning of "in the public interest." This first inquiry also raises the subsidiary question of which units within DHMH have the authority to promulgate regulations governing the dispensing permit regime for physicians, dentists, and podiatrists. Second, Mr. Souranis asked whether physicians, dentists, or podiatrists who hold permits to dispense prescription drugs may delegate any part of the dispensing process to unlicensed individuals in their practices. Finally, he asked whether the Board of Pharmacy has the power under HO § 12-604(a) to inspect the offices of practitioners who hold dispensing permits.

With respect to your first question, an agency generally may issue regulations to clarify the meaning of ambiguous statutory terms, but the regulations must be consistent with the statutory

scheme and the provisions of the Administrative Procedure Act ("APA"). The agency will thus have to consider whether any particular regulatory change would conflict with the language of the statute or its legislative history. As for which offices or units within the Department may issue regulations in this context, it is our view that the Secretary of DHMH and the Boards of Physicians, Dental Examiners, and Podiatric Medical Examiners, but *not* the Board of Pharmacy, may promulgate regulations governing the dispensing permit regime at issue.

With respect to your second question, we conclude that HO § 12-102(a)(3) prohibits wholesale delegation of the entire dispensing process but does not prohibit the delegation of specific parts of the process so long as the prescriber is on the premises and performs a final check before the drugs are given to the patient. There are, however, some implicit limits on the scope of this delegation, and the separate statutes and regulations governing physicians, dentists, and podiatrists may place additional limits on the authority of those practitioners to delegate certain tasks. For example, it appears that the Board of Physicians has prohibited physicians from delegating any of these tasks to unlicensed individuals. *See* COMAR 10.32.12.04E(4).

Finally, as to your third question, it is our opinion that the Board of Pharmacy is not authorized to inspect the offices of physicians, dentist, and podiatrists who hold dispensing permits because the General Assembly has explicitly entrusted that authority to another entity. The statute might, however, permit the Board of Pharmacy to inspect other places where drugs are "manufactured, packaged, stocked, or offered for sale" that are not within the jurisdiction of the other professional boards. *See* HO § 12-604(a).

I

Background

A. The Board of Pharmacy

The Board of Pharmacy is a unit within DHMH composed of twelve members appointed by the Governor, ten of whom must be pharmacists. HO §§ 12-201, 12-202. The Board licenses pharmacists and pharmacy technicians, evaluates whether to grant permits to particular pharmacies, and otherwise regulates the pharmaceutical profession. *See*, *e.g.*, HO §§ 12-301, 12-401, 12-6B-01; *see generally* Title 12 of the Health Occupations Article. In doing so, the Board may adopt "[r]ules and regulations to carry out the provisions of [Title 12 of the Health Occupations Article]" as

well as regulations "that are necessary to protect the public health, safety, and welfare and that establish standards for practicing pharmacy and operating pharmacies," including "[s]tandards for filling and refilling prescriptions." HO § 12-205(a)(2), (3).

The Board also has a number of investigatory powers. "During business hours, the Secretary, the Board, or the agents of either may enter any permit holder's pharmacy and inspect" the facility, its records, drugs or devices, and certain other materials "for compliance with federal and State laws and regulations." HO § 12-413(a). The Board or Secretary must conduct these inspections of Maryland pharmacies annually. HO § 12-604(b)(1). Pharmacies outside the State that do business in Maryland are subject to inspection as well. HO § 12-604(b)(2). The Board also has specific authority to inspect certain other properties over which it has licensing authority, such as wholesaler distributors' facilities. *See* HO § 12-6C-07. Moreover, the Secretary and the Board have the seemingly broader power to enter, during business hours, "any place where drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, or toilet articles are manufactured, packaged, stocked, or offered for sale" and inspect the drugs, devices, and other articles there. HO § 12-604(a).

B. A Brief History of Drug Dispensing by Prescribers in Maryland

Under Maryland law, "dispensing" means:

> [T]he procedure which results in the receipt of a prescription or nonprescription drug or device by a patient or the patient's agent and which entails the:
>
> (1) Interpretation of an authorized prescriber's prescription for a drug or device;
>
> (2) Selection and labeling of the drug or device prescribed pursuant to that prescription; and
>
> (3) Measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

HO § 12-101(h). Generally speaking, an individual may not dispense prescription drugs or devices without a license from the Board of Pharmacy. *See* HO § 12-301(a) (prohibiting the practice

of pharmacy without a license); HO § 12-101(t) (defining "practice pharmacy" to include "dispensing"). There is an exception, however, that allows a physician, dentist, or podiatrist to "personally prepar[e] and dispens[e]" her own prescriptions if she receives a written dispensing permit from the board that licenses her practice (*i.e.*, the Board of Physicians for physicians, the Board of Dental Examiners for dentists, and the Board of Podiatric Medical Examiners for podiatrists).[1] HO § 12-102(c)(2)(ii).

This exception has a long history in the United States and in Maryland. Medicine and pharmacy did not develop into separate professions in the United States until the late 1700s. *See* Richard R. Abood, *Physician Dispensing: Issues of Law, Legislation and Social Policy*, 14 Am. J. L. & Med. 307, 313 (1989). It was therefore common for physicians to dispense drugs to their own patients, rather than send the patients to a pharmacist. *Id.* Accordingly, when the Maryland General Assembly first enacted a law providing that only licensed pharmacists could fill prescriptions, it carved out an exception allowing "physicians and dentists to compound and dispense their own prescriptions." 1902 Md. Laws, ch. 179 (codified as Md. Code Ann., Art. 43 § 141 (1904)).

The practice of dispensing by physicians waned after World War II when "a general feeling emerged among physicians" that they might "be tempted to overprescribe or prescribe inappropriately only those medications which they inventoried." Abood, *supra*, at 313-14. As a result, "[p]hysician dispensing rates dropped from thirty-nine percent in 1923 to one percent in 1986." *Id.* at 314. During the mid-1980s, however, physicians began dispensing their own prescriptions more frequently because the "advent and proliferation of drug repackagers"—firms that buy drugs in bulk and repackage them in smaller amounts— made "dispensing simple, convenient, and more profitable." *Id.* at 310.

This potential profit motive again raised concerns among health professionals about whether doctors might have incentives to overprescribe drugs or prescribe only drugs that they had in stock. *See id.* at 313-14. The American Medical Association urged physicians "to avoid regular dispensing and retail sale of drugs, devices or other products when the need of patients can be met

[1] Nurse practitioners also may dispense prescription drugs under certain limited circumstances set forth in the Maryland Nurse Practice Act. *See* HO § 8-508. None of the questions you ask relates to dispensing by nurses.

adequately by local ethical pharmacies or suppliers." *Id.* at 330 n.123 (quoting AMA guidance entitled "Dispensing by Physicians Raise[s] Ethical Issues"). Many states responded by passing laws to regulate or restrict dispensing by physicians. *Id.* at 318. A handful of states banned dispensing by physicians except in limited circumstances, such as when pharmacy services were unavailable, while many other states required physicians to comply with some or all of the professional requirements imposed on pharmacists. *Id.* at 319.

In Maryland, the General Assembly reacted to these concerns by enacting the first iteration of what would eventually become the permit scheme that is now embodied in HO § 12-102(c)(2)(ii). *See* 1986 Md. Laws, ch. 691. For the first time, the statute conditioned the authority of physicians, dentists, and podiatrists to dispense drugs on the approval of the providers' respective licensing boards. *Id.* The bill as introduced provided that physicians, dentists, and podiatrists could only obtain those approvals if there were no pharmacy within a certain distance of the doctor's office. *See* 1986 Md. Laws, ch. 691. The bill was amended, however, to delete the distance requirement; as enacted, it provided merely that the physician must dispense "in the public interest." *See id.* As the Committee Report explained, "a physician would be able to apply for permission to dispense [under the statute] if he had elderly patients who might have difficulty obtaining transportation to a pharmacy." *See* 1986 Leg. Reg. Sess., Committee Report on S.B. 830. Three years later, the statute was further amended to clarify the definition of "in the public interest" and require physicians, dentists, and podiatrists to apply for formal, written dispensing permits from their respective licensing boards. 1989 Md. Laws, ch. 608.

C. Maryland's Current Permit Scheme for Dispensing by Prescribers

As the statute is currently written, a physician, dentist, or podiatrist may dispense prescription drugs to her patients under the following circumstances. As an initial matter, these practitioners may administer a single dose of a drug directly to the patient, provide a free drug sample to a patient, or dispense a starter dose of prescription medication at no charge to a patient without any special permit as long as certain other conditions are satisfied. HO § 12-102(d)-(f). More broadly, and more importantly for our analysis, a practitioner may also "personally prepar[e] and dispens[e]" her own prescriptions if (1) she applies to her

respective licensing board for a dispensing permit, (2) "demonstrate[s] to the satisfaction of that board that the dispensing of prescription drugs or devices by [her] would be in the public interest," and (3) "receive[s] a written permit from that board." HO § 12-102(c)(2)(ii).

The statute further defines the terms "personally preparing and dispensing" and "in the public interest." The former means that the permit holder "[i]s physically present on the premises where the prescription is filled" and "[p]erforms a final check of the prescription before it is provided to the patient." HO § 12-102(a)(3). The phrase "in the public interest" is defined as "the dispensing of drugs or devices by a licensed dentist, physician, or podiatrist to a patient when a pharmacy is not conveniently available to the patient." HO § 12-102(a)(2). The statute offers no guidance, however, about when a pharmacy is "conveniently available."

The Secretary of Health and Mental Hygiene (the "Secretary") has thus promulgated regulations clarifying both the application process and the phrases "in the public interest" and "conveniently available." Under these regulations, an applicant may demonstrate that granting a dispensing permit to her would be "in the public interest" by certifying that: (1) she is "thoroughly familiar" with the statutes and regulations governing the dispensing of prescription drugs and (2) she will comply with certain other requirements set forth in the regulations, COMAR 10.13.01.03B(2), including a requirement to "dispense prescription drugs to a patient only when a pharmacy is not conveniently available to the patient." COMAR 10.13.01.04J. The regulations then clarify that "[t]he decision whether a pharmacy is conveniently available shall be made by the patient based upon factors to be determined solely in the discretion of the patient." *Id*.

Additionally, a dispensing permit holder must adhere to the dispensing and labeling standards applicable to pharmacists, purchase prescription drugs from a permitted distributor, complete continuing education courses related to dispensing drugs, and allow the Division of Drug Control within DHMH to inspect his office. *See* HO § 12-102(c)(2)(ii)4. A permit is good for five years, after which it may be renewed. COMAR 10.13.01.03C.

II

Analysis

A. Whether the Board or Department May Adopt New Regulations Defining "In the Public Interest"

As described above, the statute allows a prescriber with a dispensing permit to dispense prescription drugs to her patients when it would be "in the public interest" to do so, and it defines "in the public interest" to mean "when a pharmacy is not conveniently available." *See* HO § 12-102(a)(2), (b)(2)(i). The Department's regulations, however, leave to it "solely" to the "discretion of the patient" to decide whether a pharmacy is "conveniently available." COMAR 10.13.01.04J. The Board of Pharmacy has expressed concern that these provisions essentially allow physicians, dentists, or podiatrists to dispense prescription drugs whenever their patients ask them to do so. That situation, the Board fears, does not sufficiently limit the dispensing of drugs by prescribers and could allow prescribers to pressure their patients into having their prescriptions filled at the prescriber's office instead of at a pharmacy.

You have therefore asked whether the current regulations may be amended to alter the meaning of "in the public interest" or "conveniently available." Your inquiry requires us to answer two separate but related questions: May the regulations be amended at all and, if so, by which units or offices within DHMH?

1. General Power of An Agency to Issue Regulations

Generally speaking, agencies may promulgate regulations to define ambiguous terms in the statutes that they are charged with administering. This is one of the most common ways in which agencies exercise their regulatory powers, and they may do so even in the absence of any express legislative authority. *See* 62 *Opinions of the Attorney General* 36 (1977); *see also State v. Copes*, 175 Md. App. 351, 379-80 (2007) (explaining the difference between "interpretative" regulations and regulations with the force of law based on explicit legislative authority). In fact, existing regulations already define "conveniently available" to some extent. *See* COMAR 10.13.01.04J ("The decision whether a pharmacy is conveniently available shall be made by the patient based upon factors to be determined solely in the discretion of the patient.").

There are, however, limits on an agency's power to promulgate regulations. Procedurally, the agency must adopt the regulations in accordance with the requirements of the APA. *See generally* Md. Code Ann., State Gov't ("SG") §§ 10-101 through 10-139 (2015 Repl. Vol.). In terms of substance, the regulation must be "reasonable and consistent with the letter and spirit of the law under which the agency acts," *Department of Transp. v. Armacost*, 311 Md. 64, 74 (1987), and may not "exceed[] the statutory authority of the unit," SG § 10-125(d)(2). In fact, if a regulation is challenged, a court "shall" invalidate a regulation that exceeds the agency's statutory authority. SG § 10-125(d). Any regulatory change must therefore be consistent with both the broad statutory scheme and the specific statutory definition of "in the public interest" as "when a pharmacy is not conveniently available to the patient." *See* HO § 12-102(a)(2). That leaves us with an abstract answer to your first question: Yes, an agency may enact regulations that define statutory terms so long as they do not conflict with the statute.

2. Which Units May Promulgate Regulations?

Although we conclude that the "public interest" regulations may be amended so long as the changes meet the substantive and procedural requirements of State law, we do not believe that the Board of Pharmacy is the governmental unit with the power to amend them. The Board of Pharmacy is authorized to adopt "[r]ules and regulations to carry out the provisions of [Title 12 of the Health Occupations Article]" and rules "that establish standards for practicing pharmacy and operating pharmacies," including "[s]tandards for filling and refilling prescriptions." HO § 12-205(a)(2), (3).

These provisions, taken alone, would seem broad enough to authorize the Board to issue regulations that would amend the current definitions. After all, the definitions in question were promulgated to carry out a provision of Title 12, and the rules in COMAR arguably set forth "standards for practicing pharmacy" and "standards for filling . . . prescriptions." *See* HO § 12-101(t) (defining "practice pharmacy" to include "dispensing"). But the Board of Pharmacy's regulatory authority must not be viewed in isolation; it must instead be read within the larger statutory scheme governing the dispensing of prescription drugs by other health professionals. *See, e.g., Board of County Comm'rs of Garrett County v. Bell Atlantic-Maryland, Inc.*, 346 Md. 160, 178 (1997) ("[W]e must look to the entire statutory scheme, and not any one

provision in isolation, to effect the statute's general policies and purposes.").

When the General Assembly enacted the legislation creating the dispensing permit regime at issue here, it entrusted regulatory authority over that regime to the Board of Physicians (then called the Board of Physician Quality Assurance), the Board of Dental Examiners, and the Board of Podiatric Medical Examiners. More specifically, the Legislature gave each of these three boards the express power, "[a]fter consulting with the State Board of Pharmacy, [to] adopt rules and regulations regarding the dispensing of prescription drugs by" the health professionals they license. 1986 Md. Laws, ch. 691 (currently codified at HO §§ 4-205(a)(2) (dentists), 14-205(b)(1)(ii) (physicians), 16-205(a)(2) (podiatrists)). It thus appears that the General Assembly intended that these three boards, rather than the Board of Pharmacy, would control the dispensing permit process for their respective licensees. In other words, the Board of Physicians would adopt regulations governing dispensing by physicians, the Board of Dental Examiners would adopt regulations governing dispensing by dentists, and the Board of Podiatric Medical Examiners would adopt regulations governing dispensing by podiatrists. Although all three boards were required to consult with the Board of Pharmacy about their rules, the authority to promulgate those rules was given to the non-pharmacist boards.

The apparent intent of the General Assembly to place regulatory authority with the non-pharmacist boards also comports with the understanding expressed by the interested parties in the years immediately following the statute's enactment. The Maryland Pharmacists Association, for example, pressed the General Assembly in 1989 to clarify HO § 12-102 because the three non-pharmacist boards had not yet issued any regulations on the dispensing process. *See* 1989 Leg., Reg. Sess., Hearing Before the Senate Economic and Environmental Affairs Committee on S.B. 732 (written testimony of the Maryland Pharmacists Association). The Board of Physician Quality Assurance also thought that it was responsible for issuing its own regulations and was working on draft regulations at the time. *See id.* (written testimony of the Board of Physician Quality Assurance, attaching draft regulations). And, when the Secretary ultimately proposed regulations governing the dispensing process, the notice he published in the Maryland Register specifically noted that the regulations had been "considered by" the Board of Dental Examiners, the Board of Physician Quality Assurance, and the Board of Podiatric Medical

Examiners but did not mention the Board of Pharmacy. *See* 19:1 Md. Reg. 54, 54-55 (Jan. 10, 1992); *see also* 26:24 Md. Reg. 1861 (Nov. 19, 1999) (noting that the same three boards had considered a proposed amendment to the regulations, but not mentioning the Pharmacy Board).

We think that the specific grant of regulatory authority to the boards of physicians, dentistry, and podiatry to oversee the dispensing permit regime for their respective licensees controls over the general grant of authority to the Board of Pharmacy to issue regulations under Title 12. *See*, *e.g.*, *Suter v. Stuckey*, 402 Md. 211, 231 (2007) (explaining that, in the event of a conflict between two statutes, "the more specific statute controls"). Although the broad language of HO § 12-205 might otherwise authorize the Board of Pharmacy to issue regulations in this context, we doubt the General Assembly intended to convey regulatory authority over the same administrative scheme to two different entities within the Department and thereby risk that those two entities would adopt contradictory rules governing the same conduct by the same individuals. It seems instead that the Legislature provided for the Board of Pharmacy to have input into the other boards' regulations by "consulting" with them rather than by promulgating its own competing set of regulatory requirements.

We recognize that there may be other ways in which the different boards' regulatory powers could be harmonized, at least in practice. The Secretary has the power to "review" and "revise the rules and regulations of . . . [e]ach unit in the Department," Md. Code Ann., Heath-General ("HG") § 2-104(b)(3) (2009 Repl. Vol., 2014 Supp.), and thus could revise any regulations proposed by one of the professional boards that would conflict with another board's regulations. Moreover, as we have previously observed, agencies are expected to work together to avoid these types of conflicts as much as possible. *See* 70 *Opinions of the Attorney General* 180, 186 (1985).

But here there is no evidence that the Legislature intended to put the Board of Pharmacy in direct conflict with the other professional boards and require the Secretary to resolve that conflict. In fact, the General Assembly apparently attempted to prevent that conflict from occurring in the first place by giving each individual professional board the power to grant dispensing permits to its own licensees, rather than requiring prescribers to get a permit from the Board of Pharmacy. We accordingly conclude that Board of Pharmacy does not have the authority, on its own, to adopt a regulation to clarify when a pharmacy is "conveniently available" to a patient. Rather, the boards of physicians, dentistry, and

podiatry have the express authority to issue regulations governing their respective licensees in consultation with the pharmacy board.

In addition to those three boards, however, we think the Secretary of DHMH also has the power to amend the dispensing regulations governing physicians, dentists, and podiatrists and, in doing so, could ask the Board of Pharmacy for assistance in drafting those amendments. One source of the Secretary's power to issue regulations in this context might be § 2-104(b)(3) of the Health-General Article, which, as discussed above, authorizes the Secretary to "review" and "revise" the regulations of "[e]ach unit in the Department."[2] In addition, the Secretary has broad power to "adopt rules and regulations to carry out the provisions of law that are within the jurisdiction of the Secretary." HG § 2-104(b)(1). Although the statute does not explicitly delineate which provisions are within the Secretary's jurisdiction, he has wide-ranging authority to regulate the manufacture, distribution, and dispensing of prescription drugs prescription drugs under both the Maryland Controlled Dangerous Substances Act and the Maryland Food, Drug, and Cosmetic Act.

The Controlled Dangerous Substances Act requires a person to register with the Department before manufacturing, distributing, or dispensing a "controlled dangerous substance" and criminalizes, among many other things, the dispensing of drugs without a prescription. Md. Code Ann., Crim. Law ("CR") §§ 5-301, 5-701 (2012 Repl. Vol., 2014 Supp.). The Act explicitly authorizes the Department to "enforce" the Act and "adopt regulations to implement" its provisions. CR §§ 5-201(a)(1), 5-203. Similarly, the Food, Drug, and Cosmetic Act, which regulates certain aspects of the dispensing of prescription drugs, *see* HG § 21-220, provides

[2] We say "might be" because it is our understanding that the Secretary has traditionally exercised this authority only with respect to regulatory changes that have already been proposed by a unit within the Department, not to initiate regulations on his or her own. That practice seems to be based on the recognition that the health occupations boards "are created to function as independent boards" when it comes to regulating their respective occupations, HO § 1-102(b), and that any authority over departmental units that is not "specifically granted to the Secretary by law" is "reserved to those units free of the control of the Secretary." HG § 2-106(c). Although all regulations proposed by the constituent units of DHMH are formally proposed by the Secretary on behalf of those units, *see* SG § 8-206, it is at the proposal stage of the regulatory process that the Secretary has traditionally exercised his power to "review" and "revise" those regulations.

that "[t]he Secretary may adopt rules and regulations to carry out the provisions of this subtitle." HG § 21-234(a). The Secretary also has regulatory authority over drugs under the Prescription Drug Monitoring Program, which assists prescribers and dispensers in the prevention of prescription drug abuse. HG §§ 21-2A-02(b), 21-2A-04. Finally, the Division of Drug Control, which is within the Secretary's office, plays an important role in the dispensing permit regime by inspecting the offices of permit holders to ensure that they are in compliance with the statutory requirements. *See* HO § 12-102.1(b).

We think the Secretary's general authority over health-related regulations and his more specific authority over prescription drugs mean that the dispensing process for prescribers lies within the Secretary's "jurisdiction" and that he has the power under HG § 2-104 to issue or amend regulations governing dispensing permits for physicians, dentists, and podiatrists.[3] Therefore, while the Board of Pharmacy may not issue regulations in this area on its own, the Secretary may do so and might well ask the Board for assistance in considering changes to the regulations.[4] After all, the Board of Physicians, Board of Dental Examiners, and Board of Podiatric Medical Examiners are *required* to consult with the Board of Pharmacy before they issue dispensing regulations. *See* HO §§ 4-205(a)(2), 14-205(b)(1)(ii), 16-205(a)(2).

B. Whether Physicians, Dentists, and Podiatrists May Delegate to Unlicensed Individuals the Tasks Involved in Dispensing

By statute, the process of "dispensing" a prescription drug entails at least the following steps: interpreting the prescription, selecting the proper drug, measuring the correct amount of the drug, packaging the drug, and correctly labeling the package. *See*

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[3] We do not mean to suggest that every regulation involving drugs would necessarily fall within the jurisdiction of the Secretary. The General Assembly, for example, may well have intended to delegate the regulation of the pharmaceutical profession exclusively to the Board of Pharmacy even where it overlaps with the Secretary's authority over prescription drugs. *See* HO § 1-102(b) (explaining that the health occupations boards were "created to function as independent boards" when it comes to regulating their respective occupations).

[4] The Secretary, in fact, recently asked the Board of Pharmacy to review the current dispensing regulations and make recommendations about potential amendments. *See* 41:11 Md. Reg. 614 (May 30, 2014) (DHMH proposing amendments to dispensing regulations and noting that the amendments had been "considered by" the Board of Pharmacy). The draft regulations are currently pending.

HO § 12-101(h). Pharmacists must normally conduct *all* of these tasks themselves. *See* HO § 12-101(t)(1)(ii) (defining the practice of pharmacy to include "dispensing"); *see also* HO § 12-313(b)(4) (prohibiting a pharmacist from delegating a pharmacy act "to an un-authorized individual"). A pharmacist may, however, delegate the tasks to a licensed pharmacy technician. *See* HO § 12-6B-06 (allowing registered pharmacy technicians to perform "delegated pharmacy acts"). You have asked whether physicians, dentists, and podiatrists who hold dispensing permits may similarly delegate the dispensing function or any of the relevant steps in the process.

We have already advised multiple times that a physician may not delegate the dispensing function in its entirety because the Pharmacy Act requires a dispensing permit holder to *personally* prepare and dispense the drugs. *See* 86 *Opinions of the Attorney General* 157, 163-64 (2001); 80 *Opinions of the Attorney General* 173, 178 (1995); 44 *Opinions of the Attorney General* 300, 301 (1959); *see also* HO § 12-102(c)(2)(ii). Although in each of those instances we stated our conclusion in broad terms, we have never explicitly considered whether a physician, dentist, or podiatrist could delegate individual steps in the dispensing process, such as counting the drugs, packaging them, and preparing the label, as long as the prescriber retained overall control of the process.

A dispensing permit holder must dispense the drugs "personally," *see* HO § 12-102(c)(2)(ii), but the statute defines "personally preparing and dispensing" to require only that the permit holder "[i]s physically present on the premises where the prescription is filled" and "[p]erforms a final check of the prescription before it is provided to the patient." HO § 12-102(a)(3). Section 12-102, therefore, seems to allow a prescriber to delegate specific tasks within the dispensing process as long as the prescriber is on the premises and performs a final check.[5] The

[5] The Secretary has proposed draft regulations that, if adopted, would clarify the steps a prescriber must take to fulfill his or her statutory responsibility to perform a "final check" of the prescription. These proposed regulations provide that "final check" means "the verification by the licensee that the prescription is correct before the prescription is dispensed to the patient." 41:11 Md. Reg. 614, 615 (May 30, 2014) (proposed COMAR 10.13.01.02B(2)(a)). According to the proposed regulations, "final check" includes "the assumption of responsibility for the filled prescription, including, but not limited to: (i) Appropriateness of the dose; (ii) Correct expiration date; (iii) Accuracy of drug, strength, and labeling; (iv) Verification of ingredients; and (v) Proper container." *Id*. (proposed COMAR 10.13.01.02B(2)(b)).

legislative history confirms this reading of the Pharmacy Act. As originally drafted, the definition of "personally preparing and dispensing" also required that the prescriber actually "witness the preparation of the prescription," but the bill was later amended to delete this requirement. *See* 1989 Leg., Reg. Sess., Floor Report of the Senate Economic and Environmental Affairs Committee on S.B. 732; 1989 Md. Laws, ch. 608. The statute thus appears to authorize a dispensing permit holder to delegate limited tasks in the dispensing process, such as the counting, packaging, and labeling of drugs.

Still, the statute does not specify either to whom the prescriber may delegate these tasks or how the delegation should operate. In the absence of any express statutory restrictions on delegation, the Board of Pharmacy has expressed concern about potential risks to public health if prescribers delegate some tasks to unlicensed, untrained individuals. Indeed, it would seem strange to give prescribers nearly unlimited authority to delegate to unlicensed individuals when a pharmacist may usually delegate only to a trained pharmacy technician.[6]

But we doubt the Legislature enacted these provisions with the understanding that prescribers, in the absence of statutory restrictions, would delegate these tasks indiscriminately to untrained individuals in their practice, particularly when the actions

[6] There does not appear to be any clear consensus among other states as to whether, and to what extent, physicians may delegate certain steps in the dispensing process. *See*, *e.g.*, Abood, *supra*, at 322-23 (summarizing some of the differences in this area as of 1989). The Mississippi State Board of Medical Licensure, for example, recently issued a notice reminding its physicians that they "may NOT delegate any part of" the dispensing process. *See* Letter from Mississippi State Board of Medical Licensure to Mississippi Licensed Physicians (May 22, 2013), *available at* http://www.methodistmd.org/dotAsset/3bfa0f02-2cc1-499b-9fe3-e30f51d1b15d.pdf (last visited May 20, 2015) (emphasis in original). Oregon, however, apparently allows its physicians to delegate "nonjudgmental dispensing functions" to staff assistants so long as the "accuracy and completeness of the prescription is verified by the physician." Or. Rev. Stat. § 677.089. "Nonjudgmental dispensing functions" could include "preparing the bottle or label or handing the bottle to the patient after the physician has checked its accuracy." *See* Oregon Medical Board Report Vol. 124, No. 3, at 2 (Summer 2012), *available at* http://www.oregon.gov/OMB/newsletter/Summer%202012.pdf (last visited May 20, 2015). The physician must nevertheless "determine the correct drug, confirm the contents and label of the final package or bottle, and counsel the patient." *Id.*

in question constitute the practice of pharmacy for which a license would normally be required. *See* HO § 12-101(t). Rather, the only reasonable way to read the statute is that it implicitly requires that permit holders delegate tasks only to competent individuals who have been properly trained. This is consistent with standard principles of medical ethics, which generally prohibit medical professionals from delegating tasks to unqualified individuals.[7] The General Assembly must have expected that the medical professionals in question would follow these basic ethical requirements.

We also think that the General Assembly expected the boards of physicians, dentistry, and podiatry to flesh out the requirements for the appropriate delegation of tasks involved in the dispensing process and, if necessary, to place additional limits on a prescriber's ability to delegate these tasks. After all, these boards have explicit authority to adopt regulations "regarding the dispensing of prescription drugs," *see* HO §§ 4-205(a)(2) (dentists), 14-205(b)(1)(ii) (physicians), 16-205(a)(2) (podiatrists), and they also are more attuned to specific restrictions on delegation that might be necessary for their specific professions.

The Board of Physicians, for example, has apparently determined that physicians should *not* delegate the tasks involved in dispensing to unlicensed individuals. The General Assembly has granted physicians broad authority to delegate a wide array of duties—more than just those involved in the dispensing process—

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[7] *See, e.g.*, American Med. Ass'n, Code of Ethics, Opinion 3.03, *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion303.page? ("It is ethical for a physician to work in consultation with or employ allied health professionals, as long as they are appropriately trained and duly licensed to perform the activities being requested.") (last visited May 20, 2015); American Dental Ass'n, Code of Professional Conduct, Section 2.C, *available at* http://www.ada.org/en/about-the-ada/principles-of-ethics-code-of-professional-conduct (stating that "[d]entists shall be obliged to protect the health of their patients by only assigning to qualified auxiliaries those duties which can be legally delegated") (last visited May 20, 2015); American Podiatric Med. Ass'n, Code of Ethics, BE4.0, *available at* http://apma.files.cms-plus.com/2013%20Code%20of%20Ethics.pdf ("The podiatrist reasonably delegates aspects of medical care to auxiliary health care personnel. The podiatrist shall ensure that such personnel are qualified and adequately supervised.") (last visited May 20, 2015).

to unlicensed individuals in their practices, but it has also mandated that the Board of Physicians promulgate regulations "to delineate the scope" of permissible delegation. HO § 14-306(a), (c). Those regulations, in turn, expressly prohibit physicians from delegating the task of "[d]ispensing medications" to unlicensed individuals.[8] COMAR 10.32.12.04E(4).

It is less clear to what extent dentists and podiatrists may, under their own regulations, delegate tasks involved in the dispensing process. Unlike physicians, there is no statute that gives dentists or podiatrists general authority to delegate tasks to unlicensed individuals, *compare* HO § 14-306, but there is also no express regulation that prohibits them from delegating dispensing-related tasks. Ultimately, the professional boards themselves are best equipped to determine whether delegation is permissible under their regulations, and we expect that a court would defer to those determinations. *See, e.g.*, *Maryland Transp. Auth. v. King*, 369 Md. 274, 288 (2002) (explaining that "a great deal of deference is owed to an administrative agency's interpretation of its own regulation").

We also note that, if delegation is allowed, both boards have statutes or regulations that would put limits on the delegation of the dispensing process. The Board of Podiatric Medical Examiners, for instance, has defined "unprofessional conduct" to include "[d]elegating podiatric medical responsibilities to a person when the podiatrist delegating these responsibilities knows or has reason to know that the person is not qualified by training, experience, or licensure to perform them." COMAR 10.40.08.02B(4)(e).

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[8] This regulation could be read as prohibiting a physician from delegating the dispensing function in its entirety, as opposed to discrete steps within that process. We note, however, that the Board of Physicians expressly allows delegation in one limited context. *See* COMAR 10.32.03.08B (physicians may delegate the dispensing of starter doses and drug samples to physician assistants). In any event, it is for the Board of Physicians to resolve any ambiguity about the scope of its regulations. But if the board were to interpret its regulations to allow delegation more generally, there are other regulatory limits that would apply. The board's regulations authorize a physician to delegate to unlicensed assistants "only routine technical acts" that do not involve medical judgment and "for which the assistant has been trained." COMAR 10.32.12.02B(1), 10.32.12.03A(3). Furthermore, the physician bears ultimate responsibility for the acts of the assistant, COMAR 10.32.12.03A(4), and a physician who delegates technical acts to an unlicensed assistant must always keep in mind the potential "risk to the patient." COMAR 10.32.12.03A(1).

Similarly, a dentist may be disciplined if she "violates a professional code of ethics pertaining to the dentistry profession," HO § 4-315(a)(16), and the American Dental Association's Code of Professional Responsibility provides that dentists may only delegate duties to "qualified auxiliaries" who are properly supervised. ADA Code of Professional Conduct, Section 2.C.

In sum, we conclude that § 12-102 of the Pharmacy Act allows prescribers to delegate specific tasks in the dispensing process as long as the prescriber performs a final check, delegates the tasks only to competent, trained individuals, and exercises the authority in accordance with other limits imposed by statute and regulation on the prescriber's particular profession.

C. Whether the Board of Pharmacy May Inspect the Offices of Dispensing Permit Holders under HO § 12-604(a)

The Board of Pharmacy has the express power to "[e]nter any place where drugs . . . are manufactured, packaged, stocked, or offered for sale" and "inspect" those drugs. HO § 12-604(a). On its face, this provision would seem to authorize the Board to inspect the offices of physicians, dentists, and podiatrists who hold dispensing permits because they are places where prescription drugs are "packaged" and "offered for sale." Moreover, the legislative history of § 12-604 makes clear that the Board of Pharmacy has the power to inspect more than just traditional "pharmacies." When originally enacted in 1935, the relevant provision read:

> The members of the Board of Pharmacy . . . shall have the power to inspect in a lawful manner the medicines or drugs or drug products or domestic remedies which are manufactured, packed, packaged, made, sold, offered for sale, exposed for sale, or kept for sale, in the state and for this purpose shall have the right to enter and inspect during business hours any pharmacy *or any other place* in the State of Maryland where medicines or drugs or drug products or domestic remedies are manufactured, packed, packaged, made, sold, offered for sale, exposed for sale, or kept for sale.

1935 Md. Laws, ch. 165 (emphasis added). The specific power to inspect pharmacies was moved to a different section when the Health Occupations Article was codified in 1981, but the broader power to inspect "any place" remained. *See* 1981 Md. Laws, ch. 8, at 506.

Although this history shows that the Board of Pharmacy's general inspection powers are broad, these powers do not expressly include the authority to inspect the offices of physicians, dentists, and podiatrists who hold dispensing permits. The General Assembly instead gave that specific responsibility to the Division of Drug Control ("DDC") within DHMH. *See* 1989 Md. Laws, ch. 608. Then, in 2012, the Legislature further required the DDC to inspect the office of a dispensing permit holder at least two times during the duration of the permit. *See* HO § 12-102.1(b); *see also* 2012 Md. Laws, ch. 267. As the more recent and more specific legislative provision, § 12-102.1 would seem to authorize the DDC, and not the Board of Pharmacy, to inspect dispensing permit holders. *See, e.g.*, *Suter*, 402 Md. at 231 (reasoning that the more specific statute controls in the event of a conflict); *Farmers & Merchants Nat'l Bank of Hagerstown v. Schlossberg*, 306 Md. 48, 61 (1986) (more recent statute controls).

Although, in theory, the General Assembly could have authorized both units to inspect these permit holders, the recent legislative history of the dispensing law tends to confirm our conclusion that the Legislature delegated that duty to the DDC. In 2011, the Board of Pharmacy grew concerned that the DDC was not conducting inspections with enough frequency and, more generally, that dispensing permit holders were not held to the same safety standards as pharmacists. It therefore urged the General Assembly to adopt legislation that would have required dispensing physicians, dentists, and podiatrists to get a permit from the Board of Pharmacy (in addition to the ones from their own boards) and would have given explicit inspection authority to the Board in addition to the DDC. *See* 2011 Leg., Reg. Sess., S.B. 884 (First Reader). The bill did not pass but was referred for interim study by the Senate Education, Health, and Environmental Affairs Committee. *See* 2012 Leg., Reg. Sess., S.B. 603, Revised Fiscal and Policy Note.

During the interim, representatives from the boards of pharmacy, physicians, dentistry, and podiatry met to discuss these issues and "generally agreed" upon the provisions of new legislation that was ultimately introduced in the 2012 session. *See id*. One element of this consensus legislation was to keep the inspection power with the DDC, rather than give it to the Board of

Pharmacy, but at the same time require DDC to conduct more inspections. *See* 2012 Leg., Reg. Sess., S.B. 603 (proposed § 12-102.1). As a representative from the Board of Physicians explained, the physicians felt it was important for the inspections to be done by the DDC and not by the Board of Pharmacy because the DDC is "a neutral, outside agency." *See* 2012 Leg., Reg. Sess., Hearing Before the Senate Education, Health, and Environmental Affairs Committee on S.B. 603 (testimony of Robin Bailey). During the hearings on the bill, the Board of Pharmacy proposed an amendment that would have transferred inspection authority from the DDC to the "Secretary or an agent of the Secretary." *See id.* (written testimony of the Board of Pharmacy). The Legislature rejected the amendment and instead enacted the inspection section of the consensus legislation as proposed. *See* 2012 Md. Laws, ch. 267.

The mere rejection of a proposed amendment is not necessarily strong evidence of legislative intent; there may have been other considerations that caused the amendment here to fail. But the overall legislative history indicates that the General Assembly intended that the DDC, and *not* the Board of Pharmacy, would have the power to inspect dispensing permit holders. *See NCR Corp. v. Comptroller*, 313 Md. 118, 125 (1988) ("While a committee's rejection of an amendment is clearly not an infallible indication of legislative intent, it may help our understanding of overall legislative history."). That indication is particularly strong here, where the plain language of HO § 12-102.1 indicates that the Board of Pharmacy does not hold the power to inspect the practices of dispensing permit holders and the historical record indicates that the Board has not exercised that power. *See* 77 *Opinions of the Attorney General* 110, 115 n.7 (1992) ("[W]here there are serious doubts about statutory authority for an action, coupled with an agency's longstanding failure to act upon such authority, legislative rejection of amendments designed to provide specific authority may 'strengthen' the conclusion that statutory authority is lacking.") (citing *Bosley v. Dorsey*, 191 Md. 229 (1948)).[9]

[9] We recognize that a later-enacted piece of legislation exempted a small subset of dentists from DDC inspections. *See* 2014 Md. Laws, ch. 496 (codified at HO § 12-102.1(a)). But these dentists receive special, limited dispensing permits that allow them "to dispense only prescription strength home fluoride products, dentin-enamel mineralizing products, and antimicrobial rinse." *See* HO § 12-102(h). Dentists who hold these limited permits remain subject to the Board of Dental Examiners'

We therefore conclude that the specific grant of authority to the DDC under § 12-102.1 controls over the general grant of authority to the Board of Pharmacy under § 12-604(a). Although we do not need to decide this issue here, we also note that the broad language of the statute, which states that the Board may inspect "any place where drugs . . . are manufactured, packaged, stocked, or offered for sale," could well authorize the Board to inspect other places that are not subject to the regulatory authority of a different professional board.

III

Conclusion

For the reasons discussed above, we conclude: (1) the Board of Pharmacy may not itself amend the regulations governing dispensing permit holders, but the Secretary of DHMH (and the boards of physicians, dentistry, and podiatry) may do so as long as the amendments are consistent with the statutory scheme; (2) prescribers may not delegate the entire dispensing function, but may delegate certain tasks in the dispensing process subject to the "final check" requirement in the Pharmacy Act and further restrictions and regulations imposed by their respective licensing boards; and (3) the Board of Pharmacy may not inspect the offices of prescribers who hold dispensing permits because the General Assembly has assigned that function to the Division of Drug Control.

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authority to inspect "the work authorization forms and files kept by a licensed dentist or dental laboratory," HO § 4-407(a)(1), which would seem to include the chart notations required by HO § 12-102(h)(2).